



PTO/SB/30 (08-03)

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IPW**Request
For
Continued Examination (RCE)
Transmittal**Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	09/836,613
Filing Date	April 17, 2001
First Named Inventor	John J. Hopwood et al.
Art Unit	1652
Examiner Name	Manjunath Rao
Attorney Docket Number	1192-5 DIV

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

- a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- iii. ☐ Information Disclosure Statement (IDS)
- ii. ☐ Affidavit(s)/ Declaration(s)
- iv. ☐ Other _____

2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b. ☐ Other _____

3. Fees

- The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- The Director is hereby authorized to charge any underpayments, or credit any overpayments, to
- a. ☒ Deposit Account No. **04-1121**
- i. ☒ RCE fee required under 37 CFR 1.17(e)
- ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☒ Check(s) in the amount of \$ **395.00** enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

Name (Print/Type)	Ann R. Pokalsky	Registration No. (Attorney/Agent)	34,697
Signature	<i>Ann R. Pokalsky</i>	Date	09/21/05

CERTIFICATE OF MAILING

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Name (Print/Type)	Ann R. Pokalsky	Date	09/21/05
Signature	<i>Ann R. Pokalsky</i>		

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): John J. Hopwood, et al.

Examiner: Manjunath Rao

Serial No.: 09/836,613

Group: Art Unit 1652

Filed: April 17, 2001

Docket: 1192-5 DIV

For: SYNTHETIC MAMMALIAN ALPHA-N-
ACETYLGLUCOSAMINIDASE AND
GENETIC SEQUENCES ENCODING SAME

Dated: September 21, 2005

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

**SUBMISSION UNDER 37 C.F.R. § 1.114
(REPLY TO ADVISORY ACTION)**

Sir:

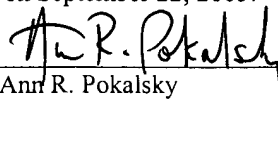
This submission under 37 C.F.R. § 1.114 is filed herewith along with a Request for Continued Examination (RCE). As defined under 37 C.F.R. § 1.114(c), a submission includes new arguments, or new evidence in support of patentability.

The last paper received from the U.S. PTO in the above-identified application was an Advisory Action from the Examiner, mailed June 28, 2005. In that Advisory Action, the Examiner indicated that Applicant's Request for Reconsideration filed on May 25, 2005, had been considered and entered. It is respectfully submitted that the paper

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8 (a)

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Dated: September 21, 2005


Ann R. Pokalsky

submitted May 23, 2005 (certificate of mail date) was an Amendment under 37 C.F.R. §1.116, not a Request for Reconsideration. In any event, the Examiner's position is that the claims are still not in condition for allowance and the previous rejections have been maintained.

The Examiner refers to the Weber et al. article (2001) *Protein Expression and Purification* 21:251-259, submitted previously by Applicants to further show differences between a tissue-derived source and the presently-claimed recombinantly produced form of NAGLU. According to the Examiner's comments on page 2 of the June 28, 2005, Advisory Action, i.e., "[w]hile the reference of Weber et al. indicates that the difference between the 79 and 89 kDa proteins is due to glycosylation, it does not indicate whether such differences exist between the purified and the recombinant enzyme."

In response to the position of the Examiner, Applicants respectfully submit that the Examiner has erred in taking the position that Weber et al. does not indicate whether differences in glycosylation exist between a tissue-derived (purified) source and the presently claimed recombinant enzyme. For example, page 257 of the Weber et al. reference specifically states:

Although the glycosylation pattern of rNAGLU seems to be slightly different when compared to enzyme purified from placenta, other characteristics are identical. Since the glycosylation is crucial for the phosphorylation we cannot exclude that the altered pattern is causing the weak dephosphorylation of the recombinant enzyme while the native enzyme is phosphorylated to the same extent as other lysosomal enzymes."

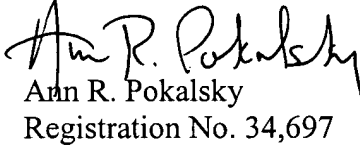
Thus, Applicants have clearly showed that the presently claimed invention is distinct from a tissue-derived source of enzyme such as that described in Weber et al. and even Sasaki et al. (1991) *J. Biochem.* 110(5):842-846 (upon which the rejection under 35

U.S.C. 102(b) is based). Inasmuch as the foregoing comments constitute new arguments and/or new evidence for patentability, the same must be considered a submission under 37 C.F.R. § 1.114, rendering the final office action non-final in nature.

Further, Applicants repeat, reassert, and incorporate by reference the "REMARKS" section of the section 116 amendment submitted on May 23, 2005, where arguments for both novelty and non-obviousness of the presently claimed invention were set forth with particularity.

Accordingly, the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


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